



June 1, 2005

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Ortho Molecular Products Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481  
715.342.9881 Phone  
800.332.2351  
715.342.9866 Fax  
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

**Name of Manufacturer:** Ortho Molecular Products, Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481

**Statement Text:** Cardiovascular Health, Essential Oils

**Dietary Ingredients:** Vitamin E (d-Alpha Tocopherol) (with Mixed Tocopherols & Tocotrienols), Tocotrienols, Gelatin, Glycerin, Oryza Oil, Nutriene Rice Tocotrienol, Purified Water.

**Dietary Supplement Name:** Tocotrienols from Rice

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Melissa Slager".

Melissa Slager  
Document Control / Training Manager  
Ortho Molecular Products

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## Attachment of Tocotrienols from Rice Labels


Suggested Use: As a dietary supplement, 2 soft gel capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep out of reach of children. † These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Because Efficacy Matters™

# Tocotrienols

From Rice



Supplement Facts		
Serving Size 1 Soft Gel		
Servings Per Container: 60		
1 soft gel contains	Amount Per Serving	% Daily Value
Vitamin E (d-Alpha Tocopherol) (with Mixed Tocopherols & Tocotrienols)	100 IU	333%
Tocotrienols	50 mg	*
* % Daily Value not established		

Other Ingredients: Gelatin, Glycerin, Oryza Oil, Nutriens™ Rice Tocotrienol and Purified Water. This product was sealed for your protection. Do not use if outer topoged neck seal or inner-seal are missing or damaged.

Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive, Stevens Point, WI 54481  
OrthoMolecularProducts.com

Label ID L-QMP100-425060-C

Also Excellent for:

Essential Oils

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Dietary Supplement Product #425

60 Soft Gel Capsules